REMARKS

Reconsideration of the rejections set forth in the Office action mailed September 5, 2003 is respectfully requested.

I. Amendments

Claim 11 has been amended to specify that the polypeptide encoded by the claimed nucleic acid sequence has an amino acid sequence selected from the group consisting of: SEQ ID NO: 15, SEQ ID NO: 16, sequences having the amino acid terminus of SEQ ID NO: 15 or SEQ ID NO: 16 and a deletion of up to 24 amino acids from the carboxy terminus, and sequences at least 70% homologous thereto. New dependent claim 25 specifies that the "sequences having the amino acid terminus of SEQ ID NO: 15 or SEQ ID NO: 16 and a deletion of up to 24 amino acids from the carboxy terminus" are selected from the group consisting of SEQ ID NOs: 25, 26, 27 and 28.

Support for these amendments is found, for example, in the specification at page 18, lines 21-28:

> ...the protein or proteins are derived from the carboxy-terminal 549 amino acids encoded by HEV ORF2 (*e.g.*, SEQ ID NO:15 or SEQ ID NO:16 or sequences homologous thereto); derived proteins may have a comparable amino terminus to the 549 amino acid protein and up to about a 24 amino acid deletion from the carboxy terminal end (*e.g.*, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27 and SEQ ID NO:28).

Support is also found at page 7, lines 10-22:

> ...a Hepatitis E Virus (HEV) polypeptide composition, consisting of at least one polypeptide derived from the carboxy-terminal 549 amino acids of HEV open reading frame (ORF) 2. The composition may include polypeptides corresponding to this region where the polypeptides have amino acids deleted from the carboxy terminus of the 549 amino acid polypeptide. In one embodiment, at least one polypeptide of the composition contains a carboxy terminal deletion of up to about 24 carboxy terminal amino acids of said 549 amino acid HEV ORF2 polypeptide. Exemplary polypeptides include, but are not limited to, the following: SEQ ID NO:15, SEQ ID NO:16, SEQ ID

NQ:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, and homologous sequences to those presented herein.

Support for 70% homology in polypeptides is found, for example, at page 16, lines 1-16.

Claims 12 and 13 are amended to recite a nucleic acid a nucleic acid sequence "as recited in claim 11", for the sake of brevity.

No new matter is added by any of the amendments.

II. Rejections under 35 U.S.C. §112, Second Paragraph

Claims 11-14 and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that it was unclear what modifications could be made to the nucleic acid sequence encoding the polypeptide recited in the claims, in view of the description of the polypeptide as "derived from the carboxy-terminal 549 amino acids of HEV open reading frame 2".

The metes and bounds of the encoded polypeptide, and thus the encoding nucleic acid sequence, have been clarified by the present amendment. Claim 11 now recites that the amino acid sequence of "a polypeptide derived from the carboxy-terminal 549 amino acids of HEV open reading frame 2" is "selected from the group consisting of: SEQ ID NO: 15, SEQ ID NO: 16, sequences having the amino acid terminus of SEQ ID NO: 15 or SEQ ID NO: 16 and a deletion of up to 24 amino acids from the carboxy terminus, and sequences at least 70% homologous thereto".

It would be clear to one of skill in the art whether a given polypeptide was at least 70% homologous (as defined in the specification; e.g. page 16, lines 1-16) to SEQ ID NO: 15 or 16, or to a sequence having the designated deletion from the C-terminus of SEQ ID NO: 15 or 16. One of skill in the art would therefore be able to determine whether a particular nucleic acid sequence encodes such a polypeptide, and thus would know whether or not the particular nucleic acid falls within the scope of claim 11 and, by extension, claims which refer to the nucleic acid of claim 11.

In view of the foregoing, the applicants submit that the amended claims comply with the

requirements of 35 U.S.C. §112, second paragraph.

II. Rejections under 35 U.S.C. §112, First Paragraph

Claims 11-14 and 18 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention without undue experimentation, for reasons of record.

In the Office Action of March 19, 2002, the Examiner contended that the language "derived from" the carboxy-terminal 549 amino acids of HEV open reading frame 2 allowed for any type of change to these 549 amino acids.

As discussed above, the metes and bounds of the encoded polypeptide, and thus the encoding nucleic acid sequence, have been clarified by the present amendment. It would be within the ability of one skilled in the art to design and prepare nucleic acid sequences encoding the range of polypeptides recited in the claim, using methods known in the art.

It would also be within the skill of such a person to use the nucleic acids, or expression systems containing them (e.g. claims 12 and 13), to produce the encoded polypeptides, and to test the polypeptides for antigenic activity. See, for example, the specification at page 43 and following ("Immunoreactivity of HEV Antigens"), which describes *in vitro* assays for evaluating the immunoreactivity of the encoded polypeptides, and at page 48 and following ("Therapeutic Applications"), which describes *in vivo* assays for evaluating the use of the encoded polypeptides for immunoprotection in animals.

In view of the foregoing, the applicants submit that the amended claims comply with the requirements of 35 U.S.C. §112, first paragraph.

IV. Rejections under 35 U.S.C. §102(e)

Claims 11-14 and 18 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,514,690 (Li *et al.*). This rejection is respectfully traversed for the following reasons.

As the Examiner pointed out, the cited patent resulted from an international application filed prior to November 29, 2000. Therefore, its effective 102(e) date is the 35 U.S.C. §371(c)(1),(2), and (4) fulfillment date.

As indicated at column 1 of the cited patent (though not on the front page), the US national

stage application having serial no. 08/617,927 was filed on March 22, 1996, not September 23, 1994 (which is the PCT filing date).

Accordingly, the cited patent is not effective as a 102(e) reference against the present application. In view of this, the applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §102(e).

V. Conclusion

In view of the foregoing, the applicant submits that the claims now pending are now in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4403.

Respectfully submitted,

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